16-Nov-18

Robert Doe, MD

Emory University

201 Dowman Drive,

Atlanta, GA 30322

Re: Medical Research Agency, Data and Safety Monitoring Board (DSMB)

Protocol 15-0045

Title: Multi-center, Randomized, Open-label Trial to Evaluate the Efficacy of Oral Fosfomycin versus Oral Levofloxacin Strategies in Complicated Urinary Tract Infections (FOCUS)

Dear Dr. Doe,

On behalf of the Medical Research Agency (MRA), we are contacting you to request your participation as the Chair of the Data and Safety Monitoring Board (DSMB) for the above-referenced protocol. Specific details regarding this protocol are included in the attached Protocol Summary.

The MRA Clinical Safety Support (CSS) staff will be working with MRA to set up and facilitate the DSMB meetings. To complete the documentation required for your participation, please review, complete, sign, and fax or email a copy of the attached Contact Information Form, and your current CV to me at 1-800-867-5309 (U.S. only) or at 301-222-4444 (International) as soon as possible. Please retain the original for your files.

It is anticipated that there will be a DSMB Organizational Meeting teleconference in March, 2019. The objectives of this teleconference include the review of the DSMB Charter, development of procedures for conducting business, and scheduling the next teleconference.

Study-related documents will be posted to a secure web server for meetings. If you choose to participate, you will be provided instructions and a username/password to access this system.

We hope that you will consider joining this DSMB and we thank you in advance for your time and expertise. If you have any questions or require any clarification related to your participation, please contact me at 301-222-3333 or via email at [css@medicalresearch.com](mailto:css@medicalresearch.com).

Sincerely,

John Smith, MS

Clinical Safety Support

Example Corporation

1234 Main Street, Suite 9001

Bethesda, MD 20817

Phone: 301-222-3333

Email: jsmith@example.com